

diagnostic test method of this invention, thus, comprises binding proteins which interact with one or more of the characteristic domains of"

Please amend page 10, lines 9 to 19 to read as follows:

"The HLE receptors on the plasma membrane of lymphocytes and mononuclear phagocytes are fairly well characterized. Thus, the epitopes characteristic of receptor structure, and their availability for accessible binding to an immunoreagent (e.g. antibody mimic), is simply a matter of choice. In one of the preferred embodiments of this invention, the immunoreagent suitable for use in the method of this invention is capable of immunochemical interaction with at least one of the catalytic triad of the HLE membrane surface proteins and the lipid interactive amino acids of the HLE membrane surface proteins. This catalytic triad of HLE (domain 1) is composed of amino acids His (41), Asp (88), and Ser (173). Lipid-interactive amino acids of the HLE (domain 2) is composed of amino acids Phe (170), Ala (187), and Arg (191); and, these amino acids are proximal to the catalytic triad. Similarly, the CD4 and chemokine receptors on the plasma membrane of lymphocytes and mononuclear phagocytes are also well-characterized."

IN THE CLAIMS:

Please cancel claims 1-8 without prejudice and add the following new claims:

9. A method for monitoring of disease progression and pathologic phenomena that correlate with surface density of Human Leukocyte Elastase (HLE) associated with plasma membranes of lymphocytes and mononuclear phagocytes, said method comprising:

A. preparing a test sample which comprises lymphocytes and mononuclear phagocytes wherein said lymphocytes and mononuclear phagocytes are capable of differentiation from other endogenous matter contained within said test sample;

- B. blocking CD4 or chemokines receptors on plasma membranes of lymphocytes and mononuclear phagocytes in said test sample by interaction of said receptors with a binding material so as to render said receptors non-reactive (competitive) relative to the HLE of the plasma membrane;
- C. contacting said plasma membranes of said lymphocytes and mononuclear phagocytes with an immunoreagent specific for interaction with HLE on said plasma membranes of lymphocytes and mononuclear phagocytes, so as to form an immunocomplex between said plasma membranes of said lymphocytes and mononuclear phagocytes and said immunoreagent including a material which when interacted with said HLE produces a characteristic physical change on the lymphocytes and mononuclear phagocytes that can be monitored;
- D. monitoring said characteristic physical changes so as to detect HLE density of said plasma membranes; and
- E. relating said HLE density to said disease progression or pathologic phenomena.

10. The method of claim 9 for determining the disease progression and pathologic phenomena resulting from microbial organisms, transplantation, autoimmunity, cancer, Acquired Immune Deficiency Syndrome (AIDS) or an Aids Related Condition (ARC).

11. The method of claim 9 wherein said immunocomplex is further reacted with another material to produce an indicator species indicative of the presence of the immunocomplex.

12. The method of claim 9 wherein said immunocomplex is monitored directly by confocal laser scanning microscopy and flow cytometry.

13. The method of claim 11 wherein said HLE density is monitored as a function of cellular response to pathologic phenomena resulting from microbial organisms, transplantation, autoimmunity, cancer or HIV infection.

14. The method of claim 9 wherein said immunoreagent is labeled with a reporter or indicator molecule capable of producing a detectable signal that can be correlated with HLE density on said plasma membranes.

15. The method of claim 14 wherein the immunocomplex is monitored by isolation thereof with a solid phase and said reporter or indicator molecule is measured by immunochromatographic analysis, radial partition immunoassay, or microparticle capture immunoassay.

16. The method of claim 14, wherein said reporter or indicator molecule is selected from the group consisting of:

- 1) a fluorescent material discernable within the visible spectra,
- 2) a material which produces such a fluorescent material, and
- 3) a material which upon interaction with a substrate forms such a
- 4) fluorescent material.